

# **IRISH HAEMOPHILIA SOCIETY**

## **TRIBUNAL NEWSLETTER**

### **ISSUE 35**

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**5<sup>th</sup> July 2001**

## **TRIBUNAL OF INQUIRY**

### **(Into the Infection with HIV and Hepatitis C of Persons with Haemophilia and Related Matters)**

#### **PROCEEDINGS: Tuesday 12<sup>th</sup> June 2001 - Day 142**

Rosemary Daly, Administrator of the Irish Haemophilia Society (I.H.S.), gave evidence today and was examined by Mr Gerard Durcan for the Tribunal.

Ms. Daly described how she had previously worked as a youth worker in Darndale in North Dublin and had subsequently got involved working with people who were infected with HIV and who were suffering from AIDS. In 1989 she joined the Irish Haemophilia Society. She described how the facilities of the Irish Haemophilia Society were primitive at that stage, with the Society operating its offices from a portacabin. However, the difficulties were made up for by the commitment and enthusiasm of the people involved in the Society.

She said that the recompense campaign, which the Irish Haemophilia Society was carrying out on behalf of people who had been infected with HIV, was to ensure that those people who had been infected had sufficient money for heating and proper nutrition. As well as the issue of finance she said there were other difficulties faced by people with haemophilia with HIV; there was fear and stigma. People were terrified of how they or their family might be treated if it was known that they were HIV positive. At this time in 1989 the Society itself was assisting people with monthly payments for heating and food. Rosemary Daly explained how, in addition to her duties in co-ordinating meetings and acting as a spokesperson for the Society, she also became heavily involved in counselling people with haemophilia. Margaret King had been employed as a full time counsellor in 1989, but the task was so great that Ms. Daly assisted her.

Ms. Daly also spoke of how she had been involved with members of the Society during litigation. She acted as a buffer between the intricacies of litigation and the people who were involved in the litigation. The Society engaged a firm of solicitors and a senior counsel to advise on the litigation. The greatest difficulty would be the cost of the litigation. Approximately £200,000.00 was the figure which was mentioned. The original estimated time for the litigation was between 18 and 24 months, but it soon emerged that it was going to take longer than this. This created a difficulty with people whose life expectancy was under threat, and being told the target date for litigation was not achievable was a devastating blow. Following an out of court settlement by people with haemophilia in the UK with the British Government, the I.H.S started to consider the possibility of pursuing an out of court settlement in Ireland. In December 1990 the Society issued a press release calling on the Government to reach a settlement for people with haemophilia. This was done in the context of members who were dying and some who had already died by this date.

In 1991, in order to put pressure on the Government, the Society put forward four candidates in Dublin constituencies for election. It was an extremely difficult thing for the candidates to do, especially considering the stigma attached to HIV at the time. Joe Dowling, Vice Chairman of the Society at the time, was himself HIV positive and agreed to go forward as a candidate. He revealed his HIV status in the course of the campaign. However, at the same time there was a meeting between the Society and its legal team. Mr. Kearns was engaged as Senior Counsel and he said that he was quite positive about the litigation. However, the solicitors in the case were not as positive and informed the Society that they were pulling out of the case. They said they were pulling out because they said they didn't feel they

would be able to handle a case that big. At this time, members of the Society were desperate to settle litigation. The Society eventually settled the litigation but it was a very much take it or leave it situation. The result of the settlement was that it brought great relief to members of the Society. It meant that members of the Society were now able to plan for the future, no matter how long or short that was going to be.

In or around 1992 and 1993 the Society was very hard pressed to raise funds to carry on its work. Not only was it trying to offer advice and information and support for its members, it was also dealing with the problems of members who had Hepatitis C or HIV.

In 1993 there were a number of meetings with the Department of Health and with doctors, in order to try and improve the services provided for people with haemophilia. In March 1993 there was an important meeting in Cork University Hospital. The Society was having difficulty trying to get the right level of communication in Cork in order to help its members get the services that they required. Arising from that meeting, they were able to establish the need for a social worker.

One matter which caused members of the Society particular pain was the use of body bags when a person infected with HIV died. In 1993 this also became an issue for somebody who had died from Hepatitis C. Rosemary Daly said that in 1993 she and Margaret King set up a critical illness service. 1993 was a horrific year; 15 people had died from AIDS related conditions that year. The critical illness service was set up to help members to look after their loved ones at home. If the person died at home they would be placed in the coffin without a body bag. Margaret King and Rosemary Daly would stay with the family and allow them and the person that had died the dignity that was deserved. Ms. Daly said that this particular year was extremely difficult. She said that the ripples of fear and anxiety went right across the community. At this time funding from the HHT was proving invaluable for the Society.

In 1994 the risk associated with hepatitis was becoming more obvious. At this time there were 150 people with haemophilia who were infected with Hepatitis C. The need for a nurse, a counsellor and a hepatologist was identified. In 1994 the Society drew up a booklet and distributed it to its members in order to answer questions about Hepatitis C.

In 1995 the Society representatives had a meeting with the Minister for Health, Michael Noonan, in order to discuss the Hepatitis C situation.

In 1996 Ms. Daly says she was involved in assisting claimants in their cases at the Hepatitis C Compensation Tribunal. She was also involved in discussions with the Government on the necessity for the setting up of the current Tribunal.

In 1999 the Cabinet passed a motion agreeing to reopen the original settlement of litigation from 1991. This was extremely important; it was important that the Government had now recognised that the original settlement was not a fair offer at all.

Ms. Daly was then examined by Mr. Bradley and gave evidence about the Haemophilia HIV Trust. The critical illness service for people with haemophilia infected with Hepatitis C is not funded from the HHT; the Deed of Trust is very specific in that funds can only be spent in relation to HIV infection. At the present time, funding of the HHT is currently practically depleted and that is a cause of concern for the Society. Funding of the Society from grants from the Department of Health is critical. In 1993, because of a shortfall of funds from the Department of Health, staff at the Society were put on protective notice. This was at a time when many people with haemophilia infected by HIV were dying.

Ms. Daly then described how achieving anything for the I.H.S. had been an uphill battle. This battle had gone right through the HIV Compensation, the Finlay Tribunal, the current Tribunal, and it had always, she said, been an uphill battle. She said that the I.H.S. is perceived sometimes to be a nuisance, but that nothing that has been achieved by the Haemophilia Society for its members has come easy.

## PROCEEDINGS: Wednesday 13<sup>th</sup> June 2001 - Day 143

The Tribunal recommenced an examination of witnesses from the National Drugs Advisory Board (the "NDAB"). Dr. Marie Byrnes gave evidence. She was appointed Deputy Medical Director of the NDAB in 1978, and held that position until 1992. Between 1992 and 1995 she was acting head of the NDAB and since that date she has worked on a part time basis. Dr. Byrnes had no direct involvement with any of the coagulation products under investigation by the Tribunal. However, since Dr. Aileen Scott, the former Medical Director of the NDAB, is now dead, and since Dr. Byrnes was the next most senior staff member in the NDAB, she agreed to give evidence to the Tribunal based on a review of files carried out by her.

Dr. Byrnes said that there were a large number of medical journals available to the NDAB. She described the working method of Dr. Scott; Dr. Scott would work most evenings and many weekends and she took no holidays. The NDAB was Dr. Scott's whole life.

Dr. Byrnes said that the risk of hepatitis was known within the NDAB throughout the late 1970s and the early 1980s. She said that the NDAB would have had general knowledge of viral hepatitis, including the risk of transmission of NANB Hepatitis and Hepatitis B through blood products. She said the risk of AIDS became known to the NDAB in June of 1983. Around this time Dr. Scott, on behalf of the NDAB, wrote to the major drugs companies asking them what precautions they were taking in relation to the transmission of AIDS in coagulation factor concentrates. A similar letter was also written to the BtSB. Dr. Byrnes gave details of the responses which were received from the pharmaceutical companies and described the steps these companies were taking to prevent the transmission of AIDS through coagulation factor concentrates. These steps involved mainly an attempt to ensure that plasma was collected from what is termed as "low risk" groups in the United States. Pharmaceutical companies informed the NDAB that they were complying with directions from the FDA in the United States in relation to the collection of plasma.

The responses of some of the pharmaceutical companies also included references to an attempt to inactivate AIDS by heat treating the products. At that stage, according to the pharmaceutical companies, there was a theory that the AIDS illness may be caused by a virus but heat treatment of the coagulation factor concentrates could lead to the inactivation of that virus. The four main pharmaceutical companies concerned were Immuno, Cutter, Armour and Travenol.

The response from the BtSB came from Dr. O'Riordan and stated that the BtSB was actively pursuing the matter and would keep the NDAB advised of developments. Dr. O'Riordan also forwarded to Dr. Scott a copy of minutes from the meeting of the Council of Europe in Lisbon, where Council members made certain recommendations in relation to the safety of blood products.

It is not clear whether the Board of the NDAB discussed the Council of Europe recommendations. There is no record of it in the minutes of any of the meetings.

Dr. Byrnes was asked about an application by Travenol to use a product on a trial basis in 1984. Travenol proposed to use the heat treated product which was made using Irish source plasma. They wrote to Dr. Scott asking for permission to do so, and Dr. Scott gave them permission. However, there was no new product authorisation sought or granted in relation to this. The normal formal administrative channels were not used in order to allow the use of this Travenol product in the country. Dr. Byrnes agreed that this was a pragmatic approach to a problem which existed at the time.

Dr. Byrnes was then asked about the Annual Report for the NDAB of 1983. A section of the report refers to AIDS and states that, "The known distribution of AIDS cases appears to parallel that of Hepatitis B virus infection", and the Board recommended that unless a blood product could be processed as to minimise the possibility of transmission of AIDS no product should be accepted for marketing which was fractionated from blood sources from areas having a high incidence of AIDS. Dr. Byrnes said that this report would have been prepared in 1984, even though it stated 1983, and that it was the practice that reports would be prepared and completed in the year following the year they were generated for. Dr. Byrnes said that this report would have been prepared by Dr. Scott. Dr. Byrnes agreed that this draft report had originally been prepared with a statement in it which said that, unless a blood product could be processed so as to exclude the possibility of transmission of AIDS. The draft report had subsequently been amended in hand writing to read that the blood product should be processed so as to exclude the possibility of AIDS "insofar as is possible" and that the statement had been marked with the note "total is not possible".

Dr. Byrnes was then asked at what date Dr. Scott became aware that a patient in Ireland had contracted AIDS. Dr. Byrnes said that the date was December 1984. Dr. Byrnes said that this information changed the whole approach of the NDAB to licensing of concentrates. She said that previously the advice would have been that both heat treated and unheat treated factors should have been available; now the advice would be that only heat treated product should be available. Dr. Byrnes agreed that at this stage in 1984, it had become a matter of priority for the NDAB.

Dr. Byrnes was then asked about a letter from Prof. Temperley to Dr. Scott in early 1985, stating that Prof. Temperley proposed to continue using BtSB manufactured cryoprecipitate and factor IX. There is no evidence to show that Dr. Scott made any follow-up in relation to the BtSB factor IX as to whether it was heat treated or not.

Dr. Byrnes was then asked about a letter from Travenol of 18<sup>th</sup> January 1984. That letter stated that Travenol was going to incorporate heat treatment of its factor VIII concentrate. Travenol stated that they thought it would be unethical from then on to treat patients with factor VIII concentrate which was not heat treated, because this may be less safe than heat treated product.

Dr. Byrnes was asked how it was possible in the light of these kinds of responses from other pharmaceutical companies, that product authorisation was granted for Miles for their Koate product which was not heat treated. This product authorisation was granted in March 1985. Dr. Byrnes said that this appeared to be an administrative error.

Dr. Byrnes was then asked about a meeting between Dr. Scott and representative of the Department of Health, where it was stated that all products on the market with the exception of products from Immuno and Miles Laboratories were now heat treated. Dr. Byrnes agreed that this was not an accurate statement, and that at this time there were no licensed heat treated products on the market. The date of this meeting was 10<sup>th</sup> January 1985. Dr Byrnes agreed that no mention was made at this meeting of the BtSB factor IX product which was not heat treated.

Dr. Byrnes was then asked about an article which appeared in the Lancet in May 1986. This was an article written by Dr. Prince of the New York Blood Center. This article recorded the fact that heat treatment which was in use by American pharmaceutical companies may not necessarily inactivate viruses in factor concentrates. The background of this article was that Dr. Prince had been retained by Armour to analyse Armour's heat treatment process. Armour were employing 60 degrees for 30 hours heat treatment. Dr. Prince discovered that this heat treatment wasn't necessarily efficacious for inactivating HIV virus in factor concentrate. However, Armour had refused to allow Dr Prince to publish

these findings; it was only subsequently when he had carried out similar tests again that he was legally entitled to publish the results.

In October 1986 Armour recalled its heat treated product from the Irish market because of fears of seroconversions. Dr. Byrnes was asked whether or not, to her knowledge, Dr. Scott would have been concerned about the danger of using this heat treated Armour product. She was asked about this particularly in the light of the fact that the article had appeared in early 1986 in the Lancet. There is no record in the NDAB files that Dr. Scott had either considered this article or had concerns about the use of the Armour product, until Armour voluntarily recalled the product in October 1986.

Dr. Byrnes was then asked whether there was any record in the NDAB files of Prof. Temperley reporting in December 1986 on seroconversion. Dr. Byrnes said there did not appear to be any record. There is no evidence on the NDAB files that Dr. Scott pursued any information given to her in relation to HIV infection in 1986 by the use of factor concentrate.

Dr. Byrnes was then asked about a letter from Cutter in October 1987 to Dr. Scott requesting permission to supply a product to Prof. Temperley for use on a named patient basis. This product was heat treated at 60 degrees for not less than 10 hours. There was a reply from Dr. Scott in November 1987 that there was no objection for the use under the direct supervision of Prof. Temperley. Dr. Byrnes was asked about the use of a named patient system. She agreed that it was a system whereby non-authorized product could be supplied to a particular patient occasionally, when it was necessary for the therapeutic benefit of the patient. The procedure required that the physician notify the board of the name of the patient and the dispensing pharmacist. A special report form should be forwarded to the doctor for completion allowing the board to maintain adequate records. Dr. Byrnes agreed that this procedure was by way of exception to the 1984 regulations. Dr. Byrnes said that the notification to the NDAB of the use of products on a named patient basis was very much on a voluntary basis. Dr. Byrnes agreed that the system operated by the NDAB had no statutory basis.

Dr. Byrnes was asked whether Dr. Scott would have been aware of the evolving state of knowledge of viral inactivation against Non-A, Non-B Hepatitis. Dr. Byrnes said that she could not be sure, but she was certainly aware, from reading articles and papers at the time, of the various methods of heat treatment which were available, and of their effectiveness against Non-A, Non-B Hepatitis. Dr. Byrnes was asked whether she knew if Dr. Scott would have been aware of two articles in particular, one from the UK Haemophilia Treatment Centres and the other from the Lancet in 1988, which dealt with the effectiveness of heat treating coagulation factor concentrates at 80 degrees centigrade for 72 hours. Dr. Byrnes said that she could not be sure, but they certainly received the Lancet at the NDAB.

Dr. Byrnes agreed that there was no policy in the NDAB of requiring pharmaceutical companies or other producers of factor concentrates to heat treat their products to 80 degrees for 72 hours in order to ensure the viral inactivation of NANB Hepatitis.

Dr. Byrnes was then asked by Mr. Giblin for the I.H.S. about an application by Armour in 1987. In October 1986 Armour had surrendered their product authorisation for heat treated factor VIII. This surrender arose when it became apparent that two patients in the UK had sero-converted following the use of this product. The product was heat treated at 60 degrees for 30 hours. It was apparent to some people at the time that heat treating at 60 degrees for 30 hours was inadequate to inactivate the HIV virus. Armour withdrew the product following the sero-conversions. In 1987 they proposed to reintroduce the product on the Irish market, having heat treated it at higher temperatures. They had surrendered their original product authorisation and Mr. Giblin asked Dr. Byrnes whether it was appropriate for them to apply for a new product authorisation. What happened in effect was that Armour renewed their old product authorisation, and that product authorisation was "reinstated" by the NDAB. Dr. Byrnes said that

she could not answer the question. She was not in a position to say whether it was appropriate for a new product authorisation to be granted or for the old product to be renewed. If a new product authorisation had been granted the application would have had to go before the committees and the board of the NDAB for approval. When the old product authorisation was reinstated there was no requirement for the application to go before either the committees or the board.

## PROCEEDINGS: Thursday 14<sup>th</sup> June 2001 - Day 144

Today, Dr. Mary McCarthy of the Irish Medicines Board, formerly the NDAB, gave evidence examined by Mr. McCann for the Tribunal.

Dr. McCarthy was a medical assessor with the NDAB from 1981 onwards until she retired in April 2000. During her time with the NDAB she was responsible for carrying out the medical assessment of the Koate product which was manufactured by Cutter.

In January 1983 Cutter wanted to supply a limited quantity of factor VIII to Pelican House. The NDAB gave Cutter permission to supply a limited amount for clinical trials. No formal application for a product authorisation had been made for this product. Throughout 1984, quantities of Koate were supplied to the BTSB while no product authorisation was in place. Dr. McCarthy said that it was her understanding that this product was supplied to the BTSB on a named patient basis. The named patient basis is the only way that product can legally be supplied into the country without a product authorisation.

In September 1984, Miles (an associated company of Cutter's) made a formal application for a product authorisation for a non-heat treated factor VIII product, Koate. Ms. Rafter, pharmaceutical assessor of the product in the NDAB, replied in September that no product authorisation would be given for non-heat treated products. Ms. Rafter agreed when giving evidence that this statement was in fact incorrect, and that she wasn't sure how this statement had been made. In any event, Miles proceeded with their application for a product authorisation for Koate.

On 9<sup>th</sup> October there was a meeting between representatives of Miles and the NDAB. This meeting appears to have been attended by Prof. Temperley as well. Dr. McCarthy explained that, because of the views of Prof. Temperley and his desire to have a non-heat treated product available on the market, it was agreed that non-heat treated product would be available on a specific named patient basis. Dr. McCarthy agreed that it was the view of the NDAB at this time that there would only be a product authorisation for heat treated Koate.

Following this meeting Prof. Temperley wrote a long letter to the NDAB, requesting that non-heat treated Koate be available on the market; he said that it was the view of treaters in the UK that non-heat treated product should still be available, and that the National Haemophilia Treatment Centre would also endorse that view.

There was a further meeting with Miles on 21<sup>st</sup> November 1984. The outcome of this meeting was that the NDAB agreed that product authorisations should be granted for the non-heat treated Koate product.

The position of the NDAB on the provision of non-heat treated products appears to have changed then between September and November: first a policy was expressed that only heat treated products would be authorised; then it was agreed in the case of Koate that the non-heat treated product could be used on a named patient basis; eventually it was agreed in November that product authorisation should be granted for non-heat treated Koate. Dr. McCarthy went on to say that in December, unfortunate news came to light about the seroconversion of a patient with haemophilia. Dr. Scott of the NDAB wrote to Prof. Temperley stating that a rumour had been brought to the attention of the NDAB of a report of a patient with haemophilia who had pneumocystis carinii. Dr. Scott had said that he was particularly concerned about this, and about the safety of blood products, and would appreciate any information that Prof. Temperley could provide. Prof. Temperley responded, giving details of the patient who was in St. James' Hospital. Arising out of this incident, the NDAB made a policy that only heat treated products should be

available on the market. This policy would be implemented from 1<sup>st</sup> January 1985. Correspondence from Cutter to the NDAB at this time shows that they were also seeking product authorisation for a heat treated Koate.

Despite the fact that in January 1985 there appeared to be a policy not to give authorisations for any non-heat treated products, the product authorisation for the Koate non-heat treated product was granted in March 1985. There is correspondence from Dr. Scott to Miles/Cutter to the effect that the application was being processed, and there is responding correspondence from Mrs. Tatt to Dr. Scott saying that they were looking forward to the receipt of the formal documents which would grant the product authorisation. Dr. McCarthy could not explain how it was possible that a product authorisation could be granted in such circumstances. She described the product authorisation being granted for non-heat treated Koate as an administrative error. She said that she had no further involvement with the product authorisation after January 1985, and that it was Dr. Scott who had dealt with it from that point on.

Mr. Giblin for the I.H.S. then examined Dr. McCarthy. He drew her attention to the fact that the original application for product authorisation for non-heat treated Koate in 1983 had been rejected by the board, on the grounds of lack of safety. There was a fear expressed by the board that the plasma was collected from high risk areas. Mr. Giblin then drew Dr. McCarthy's attention to the fact that over 2000 vials of un-heat treated Koate factor VIII had been supplied to the BTSB in 1984. Dr. McCarthy said she would have had no knowledge of the quantity of the particular product which was provided to the BTSB. Dr. McCarthy could not explain how an administrative error could have occurred which led to the issuing of product authorisation for the non-heat treated Koate. Dr. McCarthy said she had no recollection of any system being put in place to ensure that a similar administrative error wouldn't occur in the future. Dr. McCarthy could not understand why, if an administrative error had been made, Miles also made an administrative error in accepting the product authorisation.

In the afternoon Mr. Morley, a pharmaceutical assessor with the NDAB, gave evidence. Mr. Morley dealt with the pharmaceutical assessment of product authorisations for Travenol's Hemofil product range. Mr. Morley described how in 1986 there was a view in the NDAB that it was preferable to have products authorised which used Irish sourced plasma, rather than U.S. plasma. He also described how the NDAB would use NIBSC in the UK in order to test batches of products that were being released into the UK and in Ireland. It was a common requirement for the NDAB to insist that batches of products that were not being released into the UK would be tested in NIBSC in any event, before being brought onto the Irish market. However, there is no evidence that Travenol actually ever subjected the products to testing at NIBSC. Mr. Morley said he believed that end-testing of a batch of product for HIV was largely ineffectual.

Mr. Lynch of the NDAB then gave evidence. Mr. Lynch worked as an inspector in the NDAB; he joined in the mid 1980s and worked under Mr. O'Dowd who had been with the NDAB for some years. He described to the Tribunal the method of inspection that Mr. O'Dowd would carry out. For manufacturing licences and wholesale licences issued under legislation, it was necessary for the NDAB to inspect the premises where either the manufacturing or the wholesaling would be carried on. He described how Mr. O'Dowd's attitude towards these inspections was to examine the plant and machinery used for manufacture, but not to make any close analysis of the products that were being manufactured or the source or raw materials for those products.

Mr. Lynch described how Mr. O'Dowd had carried out inspections at the BTSB. The BTSB held both a manufacturing licence N225 and the wholesale licence W11 from the early 1970s right through until 1990. These licences allowed the BTSB to manufacture in wholesale products, including cryoprecipitate and factor IX. The licences were granted on a three year basis and renewed consistently for a further three years. Mr. Lynch described how regular inspections of the BTSB were not carried out, and that

often licences had been renewed without an inspection. Mr. Lynch also described how reports would be made to the NDAB of adverse reactions to drugs. He described how a product recall could be initiated arising out the report of an adverse reaction. By assessing the records of the NDAB, Mr. Lynch said that in the 1980s there were only two recalls of products. The first was a recall of Armour Factorate product in 1986; this recall was initiated by Armour after there were reports of seroconversions in people with haemophilia in the UK. He also described how there had been a recall of a batch of Koate factor VIII product, which was thought to have infected three haemophiliacs with Hepatitis B in 1986.

The Tribunal adjourned to the following morning.

## PROCEEDINGS: Friday 15<sup>th</sup> June 2001 - Day 145

Before evidence began today, Mr. Giblin made an application to the Chairperson. The application related to the hearing of expert evidence which was to begin the following week. Mr. Giblin expressed concern that, although the experts were due to begin giving evidence in the following week, no statements or supporting documentation had been delivered to any of the parties at this stage. He said that this was an extremely important stage at the Tribunal, and that adequate opportunity to prepare for it was not being afforded to all the parties. He also expressed concern about the manner in which evidence was being given in the Tribunal; he said that witnesses on the previous day had been rushed through their evidence at great speed. He said that the evidence was taken so quickly that it was impossible for observers to follow what was taking place. Mr. Giblin said that he submitted that the next phase should not begin, but should be adjourned to allow for the circulation of the statements of evidence and to allow the parties time to prepare adequately.

The Chairperson advised that the I.H.S. would be free to bring an application to adjourn any particular witness if they wished to do so. She said that the Tribunal would sit on Mondays because they had lost a considerable amount of time. She said that, while she could not describe herself as being under pressure, she said that she had to produce her report as quickly as possible and that the parties knew that. She totally rejected an allegation that evidence was being given with undue haste. Mr. Giblin said that the difficulty was that without the statements of the expert witnesses being circulated, it would be impossible for example to supply Prof. Hoots with the statements of other witnesses before he began to give evidence. The Chairperson said that if the reports or statements were circulated, Prof. Hoots could have them today. Mr. Giblin pointed out that Prof. Hoots was in Texas. The Chairperson responded that there are such things as faxes and e-mails and so forth.

The outcome of the application was that no adjournment was granted, and the situation remained that the expert evidence would begin on the following Thursday.

Mr. Lynch, an inspector for the NDAB, had given evidence in chief on the previous day and was now cross-examined by Mr. Lewis of the I.H.S. Mr. Lynch said in relation to the two products that were recalled in 1986, one was the Armour Factorate product and the other was the Miles Koate product. Mr. Lynch said that his information in relation to the recall of these two products arose from an examination of the recall register. He said that both the recalls were initiated by the pharmaceutical companies in question.

Mr. Lynch was then asked what was his understanding of the NDAB's power to require a pharmaceutical company to recall a particular product. He said that the power to recall products lay with the Minister. The Minister could recall any product if the product had a licence or a product authorisation. Mr. Lynch agreed that while the Minister had the power, it would be the NDAB who would advise the Minister that it would be appropriate to recall a product. Mr. Lynch agreed that no such suggestion was made to the Minister in the case of the Armour or the Miles products in 1986.

Mr. Lynch was then asked whether he thought it would have been appropriate for the NDAB to initiate a product recall for non-heat treated products in 1985, when it became NDAB policy to only allow heat treated products to be marketed. Mr. Lynch said that it was a complex issue and that he wasn't employed by the NDAB at the time and couldn't comment. He did, however, say that on his examination of the recall register, there was no evidence of a recall of products initiated by the NDAB at that time.

Mr. Lynch agreed that, although Mr. O'Dowd had a limited approach to inspections and had concentrated on plant and machinery, the legislation entitled the inspector to take samples of products. He agreed that it would have been possible for an inspector to take a sample of factor IX products manufactured by the BTSB, and to have that sample analysed if they so wished. He stated that this was never done. Mr. Lynch also commented on an internal memorandum in the BTSB which described the state of the facilities in the BTSB's manufacturing fractionation plant as being in a very poor situation.

Dr. Morris then gave evidence. Dr. Morris was appointed as senior pharmacist in the NDAB in 1987. Dr. Morris described the various forms of viral inactivation that he was aware of, including solvent detergent methods. Dr. Morris described how the BTSB had begun to apply for a product authorisation for its factor IX product. He accepted that it was agreed that the BTSB should have had a product authorisation for its factor IX product in the 1980s. Dr. Morris agreed that there was no record of Dr. Scott, or anybody from the NDAB, making any attempt to contact the BTSB in 1984 or 1985 to ascertain what the position was in relation to their factor IX product. Dr. Morris accepted that Dr. Scott must have known that the manufacture of factor IX was going on while there was still no product authorisation for the product.

Dr. Morris was then asked about correspondence of 1987 where it appears that the BTSB believed that they did actually have an authorisation for factor IX. Dr. Morris agreed that it was in fact the case that the BTSB did not have a product authorisation for factor IX.

Dr. Morris was then asked about an application made by the BTSB for a product authorisation for a factor VIII which was to be manufactured by Armour using Irish sourced plasma. Armour had sought an indemnity from the BTSB in relation to this product, and the BTSB had agreed to market the product under their own name. The NDAB agreed when the application for a product application was made, that there would be no need for any viral inactivation studies; the BTSB would be allowed to rely on the information already supplied by Armour for the product when it was processed and manufactured under Armour's own name. However, no product authorisation was ever granted in relation to this product.

In 1991, Dr. Scott wrote to Dr. Walsh of the BTSB, pointing out that there were no product authorisations granted for factor VIII and factor IX products which the BTSB may have been manufacturing. The BTSB at this stage in 1991 were not manufacturing their own factor IX or factor VIII products. However, they did have a contract fractionation agreement with Octapharma, for which there was no product authorisation held either by Octapharma or the BTSB. The BTSB's position was that the reason there was no product authorisation for the Octapharma product, was because there had been a considerable delay by the NDAB in issuing the product authorisations. The original application for a product authorisation by Octapharma was made in 1989. The Octapharma product was one which used a solvent detergent form of viral inactivation; the BTSB believed that this was safer against inactivating HIV and Non-A, Non-B Hepatitis. However, Dr. Morris said that there was also considerable delay on the part of Octapharma in processing the application; there were long delays in replying to queries raised by the NDAB.

Dr. Morris agreed that in 1987 and 1988 the NDAB were concerned not only about the risk of transmission of HIV through blood products, but also about the risk of transmission of NANB Hepatitis. He agreed that he would have been aware in 1987/1988 that there was an almost certainty that patients treated with dry heat treated factor concentrates would contract Non-A, Non-B Hepatitis. He said he also would have been aware that solvent detergent or pasteurisation could ensure the elimination of Non-A, Non-B Hepatitis from products. Dr. Morris agreed that the NDAB did not turn its attention to ensuring that coagulation factor concentrates which were marketed went through the most efficacious viral inactivation procedure. However, Dr. Morris went on to say that prior to 1989 on the Octapharma application, he would not possibly have been aware of the solvent detergent means of viral inactivation.

Dr. Morris said that he had no recollection of any scientific journals, including the Lancet, being distributed in 1988 which would have drawn his attention to the solvent detergent means of viral inactivation.

The Tribunal then adjourned to Monday 18<sup>th</sup> June.